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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/663,187	09/15/2003	M. Kent Shellenberger	02351.0007.NPUS01	1417

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EXAMINER

HUI, SAN MING R

ART UNIT PAPER NUMBER

1617

DATE MAILED: 03/11/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

HL

Office Action Summary	Application No. 10/663,187	Applicant(s) SHELLENBERGER, M. KENT	
	Examiner San-ming Hui	Art Unit 1617	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-11 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 1-11 is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. ____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. ____. |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date ____. | 6) <input type="checkbox"/> Other: ____. |

Handwritten signature/initials.

DETAILED ACTION

Claims 1-11 are pending.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 5 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The term "severe" in claim 5 is a relative term which renders the claim indefinite. The term "severe" is not defined by the claim, the specification does not provide a standard for ascertaining the requisite degree, and one of ordinary skill in the art would not be reasonably apprised of the scope of the invention. It is not clear what degree of severity of tremor the patient experienced would be considered as "severe".

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 1-3 and 5-10 are rejected under 35 U.S.C. 103(a) as being unpatentable over WO99/33465 ('465) in view of Moore et al. (Journal of Physiology, 2000; 529(1):273-281).

'465 teaches zonisamide as useful to treat Parkinson's disease (See the abstract).

'465 does not expressly teach zonisamide as useful in treating tremor. '465 does not expressly teach the employment of the herein claimed dosage of zonisamide for treating tremor.

Moore et al. teaches the postural and resting tremors are often associated with Parkinson's disease (See the abstract and page 273, col. 1).

It would have been obvious to one of ordinary skill in the art at the time of invention to employ zonisamide, in the dosage herein claimed, to treat tremor.

One of ordinary skill in the art would have been motivated to employ zonisamide, in the dosage herein claimed, to treat tremor. Zonisamide is known to treat Parkinson's disease. Therefore, employing zonisamide to patients with tremors associated with Parkinson's disease in a method of treating Parkinson's disease and thereby treating postural and resting tremors would be reasonably expected to be effective.

Furthermore, the optimization of result effect parameters (e.g., dosage range) is obvious as being within the skill of the artisan.

Claims 1-11 are rejected under 35 U.S.C. 103(a) as being unpatentable over US patent 4,981,867 ('867) in view of Kito et al. (Seizure, 1996;5(2):115-119).

'867 teaches a method of treating tremor, especially essential tremor. Such method comprises a compound that can depress transient calcium current in thalamic and other neurons (T current) (See col. 2, lines 61-68). '867 teaches ethosuximide as preferred compounds for treating tremor (See col. 5, lines 20-28).

'867 does not expressly teach zonisamide as the effective agent in treating tremor. '867 does not expressly teach the employment of the herein claimed dosage of zonisamide for treating tremor. '867 does not expressly teach zonisamide and a secondary agent in a method of treating tremor.

Kito et al. teaches zonisamide as useful to depress T-type calcium channel (T-current) (See page 115, the abstract).

It would have been obvious to one of ordinary skill in the art at the time of invention to employ zonisamide, in the dosage herein claimed, to treat tremor. It would have been obvious to one of ordinary skill in the art at the time of invention to employ a secondary agent, in addition to zonisamide, in a method to treat tremor.

One of ordinary skill in the art would have been motivated to employ zonisamide, in the dosage herein claimed, to treat tremor. Zonisamide is known to block or inhibit transient calcium current. Compounds that depress T-current are known to be useful in treating tremor. Therefore, employing any T-current depressing agents, including zonisamide, would be reasonably expected to be useful in treating tremor. Furthermore, the optimization of result effect parameters (e.g., dosage range) is obvious as being within the skill of the artisan.

One of ordinary skill in the art would have been motivated to employ a secondary agent, in addition to zonisamide, in a method to treat tremor. Since ethosuximide and zonisamide are known to treat tremor individually, concomitantly employing both compounds in a method of treating the very same disorder, i.e., tremor, would be obvious (See *In re Kerkhoven* 205 USPQ 1069).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to San-ming Hui whose telephone number is (571) 272-

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0626. The examiner can normally be reached on Mon 9:00 to 1:00, Tu - Fri from 9:00 to 6:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sreeni Padmanabhan, PhD., can be reached on (571) 272-0629. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



San-ming Hui
Primary Examiner
Art Unit 1617